Section 5
510(k) Summary
[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K122812
Date:	Feb 27th, 2013
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	Wuxi Jiajian Medical Instrument Co., Ltd Qinghong Rd., Ehu Town, Xishan District, Wuxi, China 214116
Contactor:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add.: Room 1706 Yuesha, No. 128 Songle Rd., Songjiang, Shanghai, China 201600 E-mail: doris_d@126.com Tel: 86 21-31261348 Fax: 86 21-37824346

2. Device Description

Proprietary Name:	Jiajian® Electro-acupuncture Stimulators (Model: WQ-10D1 and WQ-6F)
Common Name:	Electro-acupuncture Device
Classification Name:	Stimulator, Electro-acupuncture
Regulation Number:	Unclassified
Review Panel:	Neurology
Product Code:	BWK
Device Class:	Unclassified, 510(k)
Device Description:	Jiajian® Electro-acupuncture Stimulator, Model WQ-10D1, is a battery powered instrument with 3 channel outputs for acupuncture needle stimulation. The predicate device is ES-130, K081943. The output frequency and intensity for stimulation are adjustable. The stimulation time can be set. The 3 channels can output stimulation simultaneously. The device is powered by DC 9V battery, Type 6F22. When the battery has insufficient voltage (<8.5V), the light goes out. The user should replace battery. WQ-10D1 does not equip with acupuncture needles. The practitioners should select 510(k) cleared needles (with minimum diameter of 0.30mm and insertion depth of 15mm) for use.
	Jiajian® Electro-acupuncture Stimulator, Model WQ-6F, is an electro-acupuncture device, composed of a main unit and seven separate lead wires which represent 7 output channels. 4 output channels are grouped in Section A and 3 output channels are grouped in Section B. Section A and B have separate intensity and frequency adjusting knobs. The 4 channels in Section A can output waveforms simultaneously, and the 3 channels in Section B can output waveforms simultaneously, but

K122812

	Section A and Section B can not output waveforms simultaneously. The main unit is powered by DC4.5V battery (three No 1 battery, Size "D"). When the battery has insufficient voltage (<4.1V), the light goes out. The user should replace battery. WQ-6F does not equip with acupuncture needles. The practitioners should select 510(k) cleared needles (with minimum diameter of 0.30mm and insertion depth of 15mm) for use. The predicate device of WQ-6F is ES-130, K081943.
Indications for use:	Jiajian® Electro-acupuncture Stimulator, Model WQ-10D1 and WQ-6F are electro-acupuncture stimulator devices, which are indicated for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

3. Predicate Devices

Detailed comparison data is included in "Section 9 - Substantial Equivalence Discussion" of this 510(k) submission. Following are summarized comparison tables with predicate devices.

3.1 For Model WQ-10D1:

3.1.1 New device VS. Predicate device ES-130:

Parameters		**New Device**	**Predicate Device**
1.	510(k) Number:	K122812	K081943
2.	Marketing clearance date:	--	Nov 24th, 2008
3.	Device Name	Jiajian® Electro-acupuncture Stimulators, Model WQ-10D1	ES-130
4.	Manufacturer	Wuxi Jiajian Medical Instrument Co., Ltd	ITO Co., Ltd.
5.	Accessories for electro-acupuncture stimulation mode	Lead wire with alligator type connector (3 sets, in three different colors)	Lead wire with alligator type connector (3 sets, in three different colors)
6.	Intended use	Jiajian® Electro-acupuncture Stimulator is indicated for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.	ES-130 is indicated for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.
7.	Power Source(s)	DC 9V battery, Type 6F22	DC 9V battery, Type 6F22
8.	Compliance with Voluntary Standards?	IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2	IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2
9.	Compliance with 21 CFR 898?	Yes	Yes
10.	Weight (grams)	450g	160g
11.	Dimensions (mm) [W x H x D]	135x90x55mm	96mm(H)x63mm(W)x27mm(D)
12.	Housing Materials & Construction	ABS; Injection molded	ABS; Injection molded
13.	Waveform	Biphasic	Biphasic
14.	Shape	Asymmetric biphasic square wave	Asymmetric biphasic square wave
15.	Maximum Output Voltage (volts)	Low Intensity: 11V±15% @500Ω	Low Intensity: 18V±15% @500Ω

K122812

16.	Maximum Output Current (mA)		Low Intensity: 22mA ±15% @500Ω	Low Intensity: 36.0mA ±15% @500Ω
17.	Pulse Duration (μsec)	Positive	480±10% μS	100μS
		Negative	4 x (+Phase)	Not Sated in the manual
18.	Frequency (Hz) [or Rate (pps)]		0~100Hz	1~500Hz
19.	Net Charge (microcoulombs (μC) per pulse)		0μC@500Ω, + and – pulses cancel	0μC@500Ω
20.	Maximum Phase Charge, (μC)		17.2μC	7.2μC
21.	Maximum Current Density, (mA/cm², r.m.s.)		12.2mA/cm^2	25.5mA/cm^2
22.	Maximum Average Power Density, (W/cm²)		0.09W/cm^2	0.24W/cm^2
23.	Burst Mode (i.e., pulse trains) :	(a) Pulses per burst	2~250 (Intermittent wave) 2~320 (Rise-fall wave, Rise dense-fall disperse wave) 2~220 (Saw tooth wave)	N/A
		(b) Bursts per second	0.2 (Intermittent wave, Rise-fall wave, Rise dense-fall disperse wave, Saw tooth wave)	N/A
		(c) Burst duration (seconds)	2.5 (Intermittent wave) 3.2 (Rise-fall wave, Rise dense-fall disperse wave) 2.2 (Saw tooth wave)	N/A
		(d) Duty Cycle: Line (b) x Line (c)	0.5 (Intermittent wave) 0.64 (Rise-fall wave, Rise dense-fall disperse wave) 0.44 (Saw tooth wave)	N/A

3.1.2 Substantial Equivalence Discussion

Similarities between New device and Predicate Device:	Intended use, DC power source, biphasic square waveform,zero net charge, adjustable frequencies and intensity, number of output channels, standards
Differences between New device and Predicate Device:	Weight, dimensions; Output pulse width, frequency range, burst mode; The predicate device has a battery level check button, while the new device auto shut when the input power is less than 8.5V; The new device has CA-AM knob, while the predicate device has only constant amplitude
Conclusion:	The new device and the predicate device have same intended use, biphasic square waveform, zero net charge, number of output channels, adjustable frequency and intensity, complied standards. The differences between the two devices are analyzed as following: ① Burst mode: The new device has burst mode which is composed of a continuous train of impulses with a small pause in between while the predicate device has continuous train of impulses. But the basic characteristics of the burst mode of the proposed device are

K122812

	consistent with the continuous wave, so this difference does not raise new types of questions of safety or effectiveness. ② CA-AM knob: The new device uses the CA knob to output constant pulse trains, as same with the predicate device. The new device also uses AM knob to output amplitude modulated wave. This difference does not raise new types of questions of safety or effectiveness, because the physiological effectiveness of stimulation doesn't only depend on the use of constant pulse trains as those generated by the predicate device, but also can be achieved through modulated amplitude. ③ Maximum output voltage, maximum output current, output pulse width, frequency range: The new device has a lower maximum output voltage and current than Predicate device. The output pulse width of new device is higher than Predicate device while the frequency range is lower than the Predicate device. The duty cycle (pulse width*frequency) of both device is similar. Because the physiological effectiveness of stimulation is primarily dependent on delivered charge, and the maximum phase charge per pulse of the new device is a little higher than the Predicate device, so it can achieve the effectiveness. And the maximum output Charge is within the safety limit. Therefore this difference does not raise new types of questions of safety or effectiveness. ④ Maximum power density value, total maximum RMS current passed through the body are different, but the values are within the safety limit according to IEC 60601-2-10 and the safety limit regulated by FDA guidance. So the differences would not raise new safety concerns. To sum up, the new device WQ-10D1 is substantially equivalent to Predicate device of ES-130 (K081943).

3.2 For Model WQ-6F:

3.2.1 New device VS. Predicate device:

Parameters		New Device	Predicate Device
1.	510(k) Number:	K122812	K081943
2.	Marketing clearance date:	--	Nov 24th, 2008
3.	Device Name	Jiajian® Electro-acupuncture Stimulators, Model WQ-6F	ES-130
4.	Manufacturer	Wuxi Jiajian Medical Instrument Co., Ltd	ITO Co., Ltd.
5.	Accessories	Lead wire with alligator type connector (7 sets, in seven different colors)	Lead wire with alligator type connector (3 sets, in three different colors)
6.	Intended use	Jiajian® Electro-acupuncture Stimulator is indicated for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.	ES-130 is indicated for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.
7.	Power Source(s)	DC 4.5V (Three No 1 batteries, Size "D")	DC 9V battery, Type 6F22
8.	Compliance with Voluntary Standards?	IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2	IEC 60601-1, IEC 60601-2-10, IEC 60601-1-2
9.	Compliance with 21 CFR 898?	Yes	Yes

K122812

10.	Weight (grams)		1.03kg		160g
11.	Dimensions (mm) [W x H x D]		235x170x75mm		96mm(H)x63mm(W)x27mm(D)
12.	Housing Materials & Construction		ABS; Injection molded		ABS; Injection molded
13.	Waveform		Biphasic		Biphasic
14.	Shape		Asymmetric biphasic square wave		Asymmetric biphasic square wave
15.	Maximum Output Voltage (volts)		Low Intensity: 8V ±15% @500Ω 10V ±15% @2kΩ 13V ±15% @10kΩ		Low Intensity: 18V±15% @500Ω Not Sated in the manual Not Sated in the manual
16.	Maximum Output Current (mA)		Low Intensity: 16mA ±15% @500Ω 5mA ±15% @2kΩ 1.3mA ±15% @10kΩ		Low Intensity: 36.0mA ±15% @500Ω Not Sated in the manual Not Sated in the manual
17.	Pulse Duration (μsec)	Positive	Section A: Multiplier x1: 700μS±10% Multiplier x10: 500μS±10%	Section B Multiplier x1: 700μS±10% Multiplier x10: 250μS±10%	100μS
		Negative	Section A: 4 x (+Phase)	Section B 4 x (+Phase)	Not Sated in the manual
18.	Frequency (Hz) [or Rate (pps)]		Multiplier x1: 0~20Hz Multiplier x10: 0~200Hz		1~500Hz
19.	Net Charge (microcoulombs (μC) per pulse)		0μC@500Ω, + and – pulses cancel		0μC@500Ω
20.	Maximum Phase Charge, (μC)		12.4μC		7.2μC
21.	Maximum Current Density, (mA/cm², r.m.s.)		17.6mA /cm^2		25.5mA/cm^2
22.	Maximum Average Power Density, (W/cm²)		0.12W/cm^2		0.24W/cm^2
23	Burst Mode (i.e., pulse trains) :	(a) Pulses per burst	2~340 (Intermittent wave, N-Saw tooth wave) 2~400 (Rise-fall wave) 2~80 (I-Saw tooth wave) 2~380 (Rise dense-fall disperse wave, Rise disperse-fall dense wave)		N/A
		(b) Bursts per second	0.3 (Intermittent wave, N-Saw tooth wave, Rise-fall wave, I-Saw tooth wave, Rise dense-fall disperse wave, Rise disperse-fall dense wave)		N/A
		(c) Burst duration (seconds)	1.7 (Intermittent wave, N-Saw tooth wave) 2.0 (Rise-fall wave)		N/A

K122812

			0.4 (I-Saw tooth wave) 1.9 (Rise dense-fall disperse wave, Rise disperse-fall dense wave)	
		(d) Duty Cycle: Line (b) x Line (c)	0.51(Intermittent wave, N-Saw tooth wave) 0.6 (Rise-fall wave) 0.12 (I-Saw tooth wave) 0.57 (Rise dense-fall disperse wave, Rise disperse-fall dense wave)	N/A

3.2.2 Substantial Equivalence Discussion

Similarities between New device and Predicate Device:	Intended use, biphasic square waveform, zero net charge, adjustable frequencies and intensity, standards
Differences between New device and Predicate Device:	Weight, dimensions, input DC power; output pulse width, frequency range, burst mode, number of output channels; The predicate device has a battery level check button, while the new device auto shut when the input power is less than 4.1V; The new device has CA-AM knob, while the predicate device has only constant amplitude.
Conclusion:	The new device WQ-6F has same intended use, biphasic square waveform, Net charge, complied standards, adjustable frequency and intensity, with the predicate device of ES-130. The differences between the two devices are analyzed as following: ① Burst mode: The new device has burst mode which is composed of a continuous train of impulses with a small pause in between while the predicate device has continuous train of impulses. But the basic characteristics of the burst mode of the proposed device are consistent with the continuous wave, so this difference does not raise new types of questions of safety or effectiveness. ② CA-AM knob: The new device uses the CA knob to output constant pulse trains, as same with the predicate device. The new device also uses AM knob to output amplitude modulated wave. This difference does not raise new types of questions of safety or effectiveness, because the physiological effectiveness of stimulation doesn't only depend on the use of constant pulse trains as those generated by the predicate device, but also can be achieved through modulated amplitude. ③ Maximum output voltage, maximum output current, output pulse width, frequency range: The new device has a lower maximum output voltage and current than Predicate device. The output pulse width and frequency of new device have some difference with Predicate device. But both devices use normal stimulation pulse width and frequency. Because the physiological effectiveness of stimulation is primarily dependent on delivered charge, and the maximum phase charge per pulse of the new device is a little higher than the Predicate device, so it can achieve the effectiveness. And the maximum output Charge is within the safety limit. Therefore this difference does not raise new types of questions of safety or effectiveness. ④ Maximum power density value, total maximum RMS current passed through the body: The proposed device WQ-6F has 7 channels of output, however, the 4 channels in Section A and the 3 channels in Section B can not work simultaneously. The maximum output to 1 patient is 4 channels in total from Section A. The maximum RMS current passed through patient calculated is within the safety limit according to IEC 60601-2-10. The maximum power density value is also

K122812

	within the safety limit regulated by FDA guidance. To sum up, the new device WQ-6F is substantially equivalent to ES-130, K081943.

4. Safety and Effectiveness of the device

Jiajian® Electro-acupuncture Stimulators were tested and found to meet the safety standards of:

* IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995;
* IEC 60601-2-10 1987/Amendment 1 2001, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators; and
* IEC 60601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests

The output lead wires with connectors used for WQ-10D1 and WQ-6F were tested and found to comply with the clause 56.3(c) of the following standard:

* IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.

The devices were also tested basis on reduced battery capacity, and were found that the stimulus parameters were not significantly affected (less than ±10%).

The manufacturer performed risk analysis on Needle stimulations WQ-10D1 and WQ-6F according to ISO 14971.

The conclusion drawn from the testing is that the device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 11, 2013

Wuxi Jiajian Medical Instrument Co., Ltd.
% Ms. Doris Dong
Shanghai CV Technology Co., Ltd.
Room 1706, No. 128 Songle Rd
Songjiang Area
Shanghai, China 201600

Re: K122812
Trade/Device Name: Jiajian Electro-acupuncture Simulators
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: BWK
Dated: March 5, 2013
Received: March 11, 2013

Dear Ms. Dong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122812

Device Name: Jiajian® Electro-acupuncture Stimulators (Model: WQ-10D1 and WQ-6F)

Indications For Use:

Jiajian® Electro-acupuncture Stimulator, Model WQ-10D1 and WQ-6F are electro-acupuncture stimulator devices, which are indicated for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.

Prescription Use __√_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K122812